K012681

AUG 2 2 2003

510k Summary
September 12, 2002

Applicant's Name and Address:

Dentsply Ceramco
6 Terri Lane
Burlington, NJ 08016
Fax: 609-386-8282
Contact Person: Thomas B. Cameron, Dir. Q. A.

Name of Device:

Classification Name:	Implant, Endosseous
Common / Usual Name:	Dental Implant
Proprietary Name:	Ankylos
Establishment Registration Number:	1225486
Owner – Operator:	2246968
Classification:	Class III

Predicate Devices

Straumann ITI Implant (510k – 984104)
Branemark System (510k – 992937)

Description of Device

Ankylos dental implants consist of uncoated pure titanium (grade 2 per ISO 5832/II). The threaded area features a rough structure, the cervical margin is polished. The implants come packaged in a sterile double glass container for contact-free handling. The cover screw has already been mounted in the implant and is only removed prior to placing the abutment.

Intended Use of the Device

An endosseous dental implant is indicated for surgical placement in the upper or lower jaw arches, to provide a root form means for single or multiple unit prosthetic appliance attachment to restore a patient's chewing function. Implants can be placed with a conventional 2 stage surgical process with an option for transmucosal healing or they can be placed in a single stage surgical process for immediate loading. *Immediate loading is restricted to the anterior mandible, based* on 4 interforaminal placed implants, and not indicated for single, unsplinted implants. Patient must be subject for dental treatment with endosseous implants.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 2 2 2003

Mr. Thomas B. Cameron
Director, Quality Assurance
Dentsply Ceramco
6 Terri Lane, Suite 100
Burlington, New Jersey 08016

Re: K012681
Trade/Device Name: Ankylos Implant System
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Implant
Regulatory Class: III
Product Code: DZE
Dated: May 28, 2003
Received: June 2, 2003

Dear Mr. Cameron:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4613. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Susan Runner, DDS, MA
Interim Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use:

510(k) Number (if known): K012681

Device Name: Ankylos Implant System

Indications for Use:

An endosseous dental implant is indicated for surgical placement in the upper or lower jaw arches, to provide a root form means for single or multiple unit prosthetic appliance attachment to restore a patient's chewing function. Implants can be placed with a conventional 2 stage surgical process with an option for transmucosal healing or they can be placed in a single stage surgical process for immediate loading. Immediate loading is restricted to the anterior mandible, based on 4 interforaminal placed implants, and not indicated for single, unsplinted implants. Patient must be subject for dental treatment with endosseous implants"

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-The-Counter Use

(Per 21 CFR 801.109) (Optional Format 1-2-96)

Kevin Mulay for MSR

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number: K012681